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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John Kim

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

01/07/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,256	KIM ET AL.	
	Examiner	Art Unit	
	Khatol S. Shahnian-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-10-14-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. The amendment filed 9/21/2009 has been entered into the record. Specification multiple paragraphs and pages have been amended.

Status of Claims

2. Claims 1-15 are pending. Claims 11-13 are under examination. Claims 1-10 and 14-15 have been withdrawn as being directed to non-elected inventions.

Objections Withdrawn

3. Objection to the specification made in paragraph 4 of the office action mailed 3/20/2009 is withdrawn in view of amendment filed 9/21/2009.

Rejections Withdrawn

4. Rejection of claims 11-13 under 35 U.S.C. 102 (e) made in paragraph 12 of the office action mailed 3/20/2009 is withdrawn in view of arguments filed 9/21/2009.

5. Rejection of claims 11-13 under 35 U.S.C. 102 (e) made in paragraph 13 of the office action mailed 3/20/2009 is withdrawn in view of arguments filed 9/21/2009.

Rejections Maintained

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Rejection of claims 11-13 under 35 U.S.C. 102 (b) made in paragraph 8 of the office action mailed 3/20/2009 is maintained.

The rejection was as stated below:

Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wessels et al. (Infection and Immunity, vol. 66, no. 5, pp. 2186-2192, May 1998) from hereon called Wessels I.

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The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Wessels I teaches a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B, (see abstract, page 2186 and 2187). Wessels I does not explicitly disclose Fragment C; however this fragment is inherently included in whole length tetanus toxin. The prior art anticipates the claimed invention.

8. Rejection of claims 11-13 under 35 U.S.C. 102 (b) made in paragraph 9 of the office action mailed 3/20/2009 is maintained.

The rejection was as stated below:

Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wessels et al. (Journal of Clinical Investigation, vol. 86, pp. 1428-1433 November 1990) from hereon called Wessels II.

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Wessels II teaches a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B, (see abstract, page 1428 and 1429). Wessels II does not explicitly disclose Fragment C; however this fragment is inherently included in whole length tetanus toxin. The prior art anticipates the claimed invention.

9. Rejection of claims 11-13 under 35 U.S.C. 102 (b) made in paragraph 10 of the office action mailed 3/20/2009 is maintained.

The rejection was as stated below:

Claims 11-13 are rejected under 35 U.S.C. 102 (b) as being anticipated by Michon et al. (In *Streptococci* and Host. (Ed). Horaud et al. Plenum Press, New York, pp. 847-850, 1997) IDS of record.

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Michon et al. teach a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B, (see abstract, page 847). Michon et al. do not explicitly disclose Fragment C; however this fragment is inherently included in whole length tetanus toxin. The prior art anticipates the claimed invention.

10. Rejection of claims 11-13 under 35 U.S.C. 102 (b) made in paragraph 11 of the office action mailed 3/20/2009 is maintained.

The rejection was as stated below:

Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jennings et al. US 5,993,825

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Jennings et al. teach a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B; (see abstract, columns 1, 3, 4, 5 and claims). Jennings et al. do not explicitly disclose Fragment C; however this fragment is inherently included in whole length tetanus toxin. The prior art anticipates the claimed invention.

Applicants' argument and Office Response

11. The applicants have argued the above rejections together. Applicants' arguments of 9/21/2001 have fully considered but are not persuasive.

Applicants argue:

Applicants respectfully traverse the rejection of claims 11-13 under 35 U.S.C. § 102(b), for allegedly being anticipated by Wessels I, Wessels II, Michon I and Jennings. Briefly, the prior art references do not disclose all of the features of the claimed invention.

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Accordingly, the rejection should be withdrawn.

Independent claim 11 reads as follows:

A conjugated vaccine comprising an antigen that has been conjugated to Fragment C, wherein said antigen is a capsular polysaccharide.

The Examiner contends that Wessels I, Wessels II, Michon I and Jennings anticipate claims 11-13, because these references purportedly disclose all of the claimed features of the invention, including "Fragment C" of tetanus toxin. Office Action, ¶¶ 8-11. In making this rejection, the Examiner acknowledges that none of these references explicitly disclose "Fragment C," but contends that this claimed feature is inherently disclosed by the description in these references of a conjugate vaccine in which a capsular polysaccharide is conjugated to tetanus toxin. According to the Examiner, the disclosure of the tetanus toxin discloses Fragment C, "because this fragment is inherently included in full length tetanus toxin." However, the Examiner's reading of the claims is inconsistent with the teachings of Applicants' specification, and therefore improper in view of well-established case law from the Court of Appeals of Federal Circuit (CAFC). In particular, the CAFC has held that the claims are to be determined "in light of the specification." For example, in *Phillips v. AWH Corl2.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005), the CAFC stated that Here, Applicants' originally filed specification clearly discloses that Fragment C does not refer to the entire tetanus toxin molecule:

Thus, in the context of the present invention, Fragment C refers to separation of the region from at least a portion of the remainder of the whole tetanus toxoid molecule, which can be done by digestion of the toxoid with papain or other proteases or through recombinant expression of the fragment.

Original specification, ¶[22]. Thus, the Examiner's reading of the term "Fragment C" in claim 11 to encompass the full length tetanus toxin molecule plainly contradicts the teachings of the specification as they would be interpreted by one of ordinary skill in the art. In other words, one of ordinary skill in the art would understand, based on the specification, that the phrase "an antigen that has been conjugated to Fragment C" in

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claim 11 does not refer to conjugating the antigen to a full length tetanus toxin. The Examiner's interpretation of the term "Fragment C" contradicts the specification and is therefore inconsistent with well-established CAFC case law.

In response to applicants' arguments the applicants' attention is brought to the language of claim 11:

A conjugated vaccine **comprising** an antigen that has been conjugated to Fragment C, wherein said antigen is a capsular polysaccharide.

The **comprising** language of claim does not exclude other portions of tetanus toxoid molecule, since whole tetanus toxoid molecule includes "Fragment C" inherently. The references still anticipate the invention. MPEP 2111[R-5] recites that claims must be given their broadest reasonable interpretation.

New Rejections

Claim Rejections - 35 USC § 102

12. Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bixler et al. US 5,785,973

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Bixler et al. teach a conjugate vaccine comprising an antigen that has been conjugated to Fragment C of tetanus toxin, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B; (see abstract, column 33, table 13 and claims). The prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

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matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 11-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Michon *et al.* US 6,602,508 B2 in view of Fairweather *et al.* US 5,443,966 both IDS of record.

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Michon *et al.* teach multivalent GBS conjugate vaccines comprising the multivalent conjugates, wherein different types of GBS capsular polysaccharides including types I, II, III, IV and V are conjugated to a single protein, such as tetanus toxin (see abstract, claims, and columns 3 and 9). Michon *et al.* explicitly do not teach Fragment C, however, this deficiency has been overcome by the teachings of Fairweather *et al.*

Fairweather *et al.* teach a process for producing fragment C of tetanus toxin and conjugate vaccine (see abstract, claims, columns 1, 3 and 5). Fairweather *et al.* a 50 kD polypeptide as fragment C generated by papain digestion from 1315 amino acid tetanus toxin. (see column 1, lines 50-65). Fairweather *et al.* teach vaccine which

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comprises fragment C and may include other antigens to provide a multivalent conjugate vaccine (see column 3, lines 20-24).

It would have been *prima facie* obvious to one of skill in the art to combine the teachings of Michon et al. and Fairweather et al. to obtain the claimed invention. One of skill in the art would have been motivated by the teachings of Fairweather et al. to use fragment C and conjugate it to a capsular polysaccharide of *Streptococcus* group B because Fairweather et al. teach vaccine which comprises fragment C and may include other antigens to provide a multivalent conjugate vaccine (see column 3, lines 20-24).

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S. Shahnian-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on Mon, Wed 12:30-6:30 pm, Thur-Fri 12:30-4:30pm pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on (571)-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Khatol S Shahnan-Shah/

Examiner, Art Unit 1645

December 30, 2009

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645